NOTE: Still open, last updated 7/12/01.

December 23, 1999

OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)

PROGRAM ANNOUNCEMENT: STROKE

VA QUERI
Quality Enhancement Research Initiative

Investigator-Initiated Research
Priorities in Stroke Prevention and Management

1. **Purpose.** The Department of Veterans Affairs (VA) is focusing major resources and energy to improve the quality of the health care it provides and to create improvements that are measurable, rapid and sustainable. With the inauguration of the Quality Enhancement Research Initiative (QUERI) in early 1998, special emphasis has been placed on linking evidence to practice in clinical areas that are prevalent in VA including chronic heart failure, ischemic heart disease, diabetes, substance abuse, stroke, mental health (depression, schizophrenia), spinal cord injuries, and HIV/AIDS. For each of these areas, QUERI participants identify gaps in science and practice, compare existing to evidence-based practice, find ways to fill gaps, and translate research findings into patient outcome and system-wide improvements. Additional information about QUERI is available on the VA web page at http://www.va.gov/resdev.

2. **Synopsis.** In order to enhance the quality of care and the quality of life for veterans who have suffered a stroke or are at risk of stroke, this announcement invites Investigator Initiated Research (IIR) proposals in four areas: 1) evaluation of intervention effectiveness and compliance issues related to hypertension; 2) evaluation of the effectiveness of decision support tools designed to promote best practices; 3) development and testing of Health Related Quality of Life measures for stroke; and 4) comparison of stroke outcomes across VA facilities and VISNS.

   Projects may not exceed four years or total costs of $750,000. HSR&D is especially interested in projects that can demonstrate results in a short time (within about 18 months) and deliver tangible products that may be used by decision-makers to promote best practices. Projects require an approved Letter of Intent (LOI) consistent with regular IIR policy. Proposal due dates are May 1 and November 1, starting May 1, 2000, until further notice.

These IIR projects comprise part of a comprehensive and merit-approved strategic plan for stroke quality of care. Investigators interested in this area also should consider two research solicitations that cut across the QUERI conditions identified in paragraph 1, above. Specifically, HSR&D welcomes LOIs relevant to the implementation of clinical practice guidelines and patient centered care related to stroke and has issued announcements entitled "QUERI: Common Issues in Implementation of Clinical Practice Guidelines" and "QUERI: Patient-Centered Outcomes," both available on the VA web page at http://www.va.gov/resdev/hsr-sols.htm.

3. **Background.** Stroke is the third leading cause of death in the U. S. and a major cause of morbidity and functional impairment. Each year approximately 750,000 people suffer strokes and nearly one in five die. Three million stroke survivors live with various degrees of neurological impairment. Residual deficits from stroke affect patients physically, psychologically, and economically. In VA, approximately 15,000 veterans annually receive acute inpatient care for stroke. Approximately 70% of stroke survivors receive rehabilitation care at an estimated cost of $40 million. Strokes and related diseases consume 5% of VA patient care resources.

4. **Content Areas.** HSR&D seeks proposals on:

4a. Evaluation of intervention effectiveness and compliance issues related to hypertension

Achieving adequate blood pressure control for patients with hypertension is the single most important modifiable risk factor for stroke prevention, yet compliance is difficult to achieve.

A significant body of research has shown that public awareness campaigns and health systems interventions lead to improved detection of hypertension. Treatment options are also widely available and supported by high quality evidence. Adequate blood pressure control with drugs clearly lowers stroke rates and improves survival. A decrease in diastolic blood pressure of 5 to 6 mm/Hg results in a 42% reduction in the risk for stroke. Moreover, guidelines authored by the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure (1997) are widely accepted by clinicians and researchers. Despite the availability of evidence, blood pressure control continues to be a serious problem.

Although adequate epidemiologic and therapeutic evidence of the benefits of adequate blood pressure control exists, recent studies have highlighted that less than half of patients diagnosed with hypertension and having access to providers and medications ever achieve acceptable control. Determinants of poor blood pressure control are thought to be multifactorial and include patient compliance with prescribed regimen, lack of perceived risk either on the patients' or providers' part, and poor systems for follow-up. Additionally, age and cultural factors may play a role.

There has been relatively little research documenting which of the many possible factors account for the low overall control rates. Except for interventions that promote medication compliance, no interventions have been documented to sustain improvements in hypertension control.

Proposed studies should test the effectiveness of using an intervention(s) in real situations. Examples of research questions are:

a) What diverse characteristics and processes predict blood pressure control?

b) Can interventions targeted at medication compliance improve blood pressure control?

c) Can provider feedback result in enhanced blood pressure control?

d) Can interventions that enhance patient participation in blood pressure measurement improve control?

For references related to intervention effectiveness and compliance issues related to hypertension, see Appendix A.

4b. Evaluation of the effectiveness of decision support tools designed to promote best practices

Implementation of evidence-based recommendations in the care of acute stroke patients presents special challenges. One promising approach to improving evidence-based practice involves the use of decision support tools. The use of tools to promote adherence to evidence-based clinical practice guidelines is one way to improve clinical decision making, thus contributing to improved patient outcomes and system-wide change.

While a full range of resources is available for stroke care, there is wide variability in the number of patients presenting with stroke at each VA facility and there are significant differences in stroke treatment practices across facilities and VISNs. Decision support tools potentially reduce variation and contribute to improved quality. These tools are designed to promote best practices by providing accurate, current information to decision-makers in useful formats when it is needed.

Proposals are sought that evaluate existing decision support tools relevant to acute stroke care. Fewer than 40% of patients are admitted to a VA facility within 24 hours of symptom onset; therefore any decision support system should not focus exclusively on the hyper-acute phase. Decision support tools that promote best practices relevant to acute stroke care come in a variety of forms, including paper-based approaches such as critical paths, or computer-based systems. All computer-based tools must be compatible with the VA computer system (or easily adapted).

Proposals responsive to this solicitation will evaluate factors relevant to successful tool implementation, including provider acceptance of the tool, proficiency of use, compliance with VA stroke care guidelines, and/or resource use. Data about these factors should be linked to outcome and/or organizational information. The proposal must provide information about the potential contribution of the tool to patient outcomes and/or to system-wide quality improvements. This solicitation is not intended to fund tool development beyond tailoring to permit use in the VA. A proposed tool should have clear links to scientific evidence and should have a mechanism by which it can be updated to accommodate new information. Examples of research questions include:

a) How much can a systematic approach to stroke management based on use of a decision support system improve the outcome of patients hospitalized for stroke?

b) What is the cost-effectiveness ratio for a decision support-based approach to stroke care compared to usual care that does not actively utilize a decision-support approach?

References relevant to evaluation of the effectiveness of decision support tools designed to promote best practices are available in Appendix B.

4c. Development and testing of Health Related Quality of Life (HRQOL) measures for stroke

Despite the high prevalence and cost of stroke, there is lack of professional agreement about the best way to measure stroke outcomes. Stroke outcomes are difficult to quantify because of the wide range of stroke signs and symptoms, the different levels of stroke severity, and the language and cognitive deficits that commonly accompany stroke. In addition, increased emphasis is being placed on measuring outcomes from the patient's perspective. HRQOL is a conceptual model often employed in patient-centered outcome assessment. Because stroke frequently affects the three key domains of HRQOL (physical, psychological and social well-being), HRQOL is an appropriate model. However, valid and reliable HRQOL instruments are not available to measure stroke outcomes and little is known about the broad applicability of existing, generic HRQOL measures for stroke.

Current research often employs generic HRQOL measures like the SF-36 or the Euro-Qol. Few studies provide data about hemorrhagic strokes. While generic HRQOL measures permit comparison of patients with different diseases, they are less sensitive to the effects of particular impairments on HRQOL or response to treatment in an individual with a specific disease. Many generic HRQOL measures do not assess relevant domains like hand function, language or cognition. Generic measures have proven insensitive for differentiating individuals with mild stroke from those with TIA.

Stroke-specific HRQOL measures have recently been developed but the reliability and validity of these scales have not been established in large heterogeneous groups of stroke patients. In order to identify and test interventions that improve the HRQOL of veterans with stroke, further work is needed in assuring the accuracy of HRQOL measures.

This solicitation seeks research that will: 1) develop and test valid and reliable HRQOL measures that fill existing gaps in stroke research; 2) test the validity, reliability and generalizability of existing HRQOL measures in post stroke populations; and/or 3) evaluate the psychometric characteristics of existing HRQOL measures in post stroke populations. Examples of research questions are:

a) What are the psychometric properties (e.g. reliability, validity) of available HRQOL measures in a large, heterogeneous cohort of stroke patients?

b) Do different modes of administration of HRQOL measures produce similar results?

c) Is proxy completion of HRQOL measures reliable and valid, and are there systematic differences between patients and proxy responses?

d) At what intervals after stroke should HRQOL outcomes be assessed?

e) What factors influence the measurement of HRQOL outcomes, for example, are patient factors, stroke-specific factors, or environmental factors influenced? Do HRQOL measures predict other important outcomes including mortality, recurrent stroke, or utilization?

f) Are measures of HRQOL consistent across different stroke types?

References relevant to the development and testing of HRQOL measures for stroke patients are available in Appendix C.

4d. Comparison of stroke outcomes across VA facilities and VISNs

Proposals are sought that do at least one of the following: 1) analyze the influence of patient and/or environmental factors on functional outcomes of stroke; 2) compare stroke outcomes across VA facilities and VISNs; 3) determine predictors of appropriate level of rehabilitation; and/or 4) quantify stroke outcomes for veterans across multiple service delivery settings.

To assess VA's effectiveness in treating stroke, appropriate quality of care measures include mortality, complication rates, change in functional status and health-related quality of life. However, *unadjusted* measures are not sufficient to assess quality. In-depth understanding of case-mix (e.g., demographics, severity of illness, comorbidities) and development of a risk-adjustment methodology are necessary for determining whether facilities with poorer outcomes deliver substandard care or serve a more severely impaired population.

HSR&D currently supports research focused on developing risk-adjusted outcome models for post-stroke rehabilitation, including patient characteristics and comorbidities as risk factors. Investigators have examined the association between stroke outcomes and predictors such as referral source, rehabilitation characteristics, patient characteristics, and facility characteristics. Research is needed to compare stroke outcomes across VA facilities and VISNs. One study (Reker, 1998) assessed variations in stroke outcomes and created a case-mix adjustment model for stroke rehabilitation in VA medical centers, using data from 1993 to 1996. Additional research of this type is needed.

In 1995, the Agency for Health Care Policy and Research published guidelines with information about rehabilitation services for stroke patients, but there have been no systematic evaluations exploring the impact of these guidelines on patients and system outcomes in VA. Additional needed areas of study include:

a) What are the predictors of stroke-related outcome(s) (e.g., mortality, community discharge, functional gain, length of stay, and costs)? Do the predictors differ within case-mix adjusted groups and for various outcomes?

b) How much of the observed variation in these outcomes is determined by patient characteristics, environmental factors, or hospital/provider characteristics?

c) Are models of stroke outcome valid? What information is gained by evaluating differences in quality of care among hospitals and VISNs? How can this information be used to promote outcome and system-wide improvements?

d) Are stroke patients receiving comparable levels of rehabilitation care by qualified providers within and between VISNs? Does level of care influence outcome(s)?

e) To what extent do evidenced-based clinical practice guidelines for post-acute stroke affect patient and system outcomes?

f) Are there patient groups, VISNs, or regions within the VA that are at risk for over- or under-treatment of stroke?

g) What components of post-acute care have the most positive influence on quality of life?

References related to the comparison of stroke outcomes across VA facilities and VISNs are available in Appendix D.

5. **Research Methods.** All HSR&D studies are expected to use a rigorous and efficient research design including methods that maximize the validity, reliability, generalizability, and usefulness of findings in real situations. While the research needs to be grounded in the realities of VA practice and address real world information needs, it also needs to have a clear theoretical framework, demonstrate familiarity with the pertinent literature, and employ a data collection and analysis strategy that will yield valid conclusions. The multidisciplinary nature of health services research needs to be evident in the formulation of the research questions. Study teams should generally include individuals with experience and expertise in clinical and non-clinical fields, including pertinent social scientists and research methodologists. The research design needs to maximize the eventual application of findings and conclusions. The study should be relevant to U.S. veterans and should add new knowledge based on an appropriate conceptual framework and appropriate research design and methods, including adequate controls and statistical power. Proposals should include appropriate stroke outcome measures such as impairments, morbidities, activity limitations (disability), quality of life, satisfaction with care, and resource use (e.g. readmission, length of stay, institutional care). The outcomes to be assessed must also be clearly identified and justified in terms of their relevance to quality of care. The proposal should describe how these outcomes will be defined, measured, and evaluated.

   Studying the effectiveness of the specific interventions should be justified in terms of what is already known. HSR&D is especially interested in projects that will result in the development of products (tools) and the identification of patient outcomes within approximately 18 months. The expected products and outcomes to be disseminated upon completion of the study should be clearly explained in the proposal. Products of interest to HSR&D might include impact documents, factsheets, algorithms, patient brochures, or other tools that can be made available to decision-makers as part of routine clinical practice. Special consideration will be given to those proposals that specify how the study output (products and/or outcomes) will be translated into patient improvements or organizational efficiencies.

6. **Investigator Eligibility.** The Principal Investigator must be at least a 5/8^{ths} VA employee at the applicant site. Co-investigators, consultants, and support staff may be non-VA employees. Any questions about eligibility may be referred to Ms. Caryn Cohen at 202-273-6812 or caryn.cohen@mail.va.gov.

7. **Letter of Intent.** All applicants are required to submit a Letter of Intent (LOI) clearly designated "QUERI-Stoke" with reference to the specific content area. Additional instructions are available on the health services research web page at http://www.va.gov/resdev). Only applicants whose LOI is approved by HSR&D may submit a full proposal.

8. **Proposal Preparation and Submission.** Proposals submitted in response to this announcement will be accepted for the receipt dates of May 1 and November 1, starting in May 1, 2000, and continuing until further notice. LOIs should be submitted at least 3 months

prior to the intended date for proposal submission. Proposals should be prepared in accordance with HSR&D's "Instructions for Preparing Investigator-Initiated Research Proposals" (available at R&D offices and on the VA research home page at http://www.va.gov/resdev). Copies of both the LOI and the LOI approval letter must be included with submitted proposals.

9. **Proposal Review.** Proposals received in response to this announcement will undergo peer review, along with other IIR projects, by the HSR&D Scientific Review and Evaluation Board (SREB). The review is rigorous and the standards are very high. Scientific merit, expected contribution to improving VA health services, and other factors are considered. Investigators are expected to describe their research plan completely. Proposals recommended for approval will be considered for funding by the Director, HSR&D.

10. **Project Funding.** Studies submitted in response to this solicitation may not exceed four years or total costs of $750,000. Both short-term and long-term projects may be proposed, but HSR&D is especially interested in projects that demonstrate results in the shortest time possible and produce products that contribute to best practices. For projects that require more than two years, investigators are strongly encouraged to identify major milestones for which interim results and products can be reported and disseminated. In planning project budgets, applicants are reminded to adhere to R&D guidelines regarding allowable use of research funds.

11. **Coordination with QUERI.** Principal Investigators will submit annual progress reports and other updates as requested by the Director, HSR&D, who will provide this information to the Stroke QUERI Coordinating Center. The Stroke QUERI Executive Committee is available to provide technical consultation to investigators. **Contacting the Stroke QUERI is optional and is not a requirement of this solicitation.** Investigators who would like assistance should send a one-page letter to Eugene Oddone, MD, MHSc, Director, Center for Health Services Research in Primary Care (152), VA Medical Center, 508 Fulton Street, Bldg, 16, Room 70, Durham, NC, 27705. The letter should include the following information: name, address, and affiliation of the principal investigator, study title, type of assistance requested (e.g. statistical consultation, information on other relevant VA programs or resources, information on database availability, feedback on a draft proposal or LOI) and a brief overview of the project, especially those aspects related to the consultation request.

12. **Mailing Addresses.** It is the investigator's responsibility to confirm receipt of documents mailed in response to this solicitation. Letters of Intent (LOIs) should be submitted to:

HSR&D Service (124I)
QUERI: Investigator Initiated Research
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420

Proposals submitted under this initiative may be submitted by regular mail or Federal Express. The approved LOI and the approval letter must be included with the proposal when submitted. Submit proposals to:

HSR&D Service (124F)
QUERI: Investigator Initiated Research
Department of Veterans Affairs
1400 Eye Street, Suite 700
Washington, DC 20420

13. **Inquiries.** For further information regarding this solicitation, contact Lynn McQueen, Dr.P.H., R.N., Associate Director for QUERI at 202-273-8227 or by email at lynn.mcqueen@mail.va.gov.

John R. Feussner, M.D.
Chief Research and Development Officer

Attachment

Appendix A
References for Hypertension Control (4a)

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Appendix B
References for Decision Support (4b)

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Appendix C
References for HRQOL (4c)

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Appendix D
References for Stroke outcomes across VA facilities and VISNs (4d)

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